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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/522,436	09/06/2005	Silvio Aime	57708/380	7608

35743 7590 04/18/2007

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EXAMINER	
SCHLIENTZ, LEAH H	
ART UNIT	PAPER NUMBER
1618	

SHORTENED STATUTORY PERIOD OF RESPONSE	NOTIFICATION DATE	DELIVERY MODE
3 MONTHS	04/18/2007	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Notice of this Office communication was sent electronically on the above-indicated "Notification Date" and has a shortened statutory period for reply of 3 MONTHS from 04/18/2007.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

klpatent@kramerlevin.com

Office Action Summary	Application No.	Applicant(s)	
	10/522,436	AIME ET AL.	
	Examiner	Art Unit	
	Leah Schlientz	1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-13 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 1-13 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on 1/20/05 is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date 1/20/05.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Specification

The disclosure is objected to because of the following informalities: the application contains Figures 1 – 7, however there is no "Brief Description of the Drawings" section in the specification. See MPEP 608.01. Appropriate correction is required.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 4, 6, and 8 – 10 are rejected under 35 U.S.C. 102(b) as being anticipated by Tokumitsu *et al.* (*STP Pharma Sciences,* 2000, 10(1), p. 39 – 49.)

Tokumitsu discloses gadolinium-loaded chitosan particulate devices (abstract). Chitosan is a polysaccharide which has been widely studied due to its bio-erodible, biocompatible bioadhesive, and bioactive characteristics (page 40, column 1). Gadopentacetic acid (Gd-DTPA) chitosan microspheres were prepared from Gd-DTPA, which has anionic charges, and crosslinked chitosan, which has amino groups. The particles may have a varying Gd/chitosan ratio and a variety of sizes (pages 40 – 41).

With respect to the limitation in claim 1, wherein the particles are "administered as MR-Imaging Probes, administered in form of particulate which is internalized by cells where they are degraded enzymatically or by effectors in the environment surrounding them, giving rise to water soluble MR-Imaging Probes," it is noted that the instant claims are product claims and the recitation of method steps such as administering, etc. are not given patentable weight in product claims. The intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. See *In re Casey*, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 136 USPQ 458, 459 (CCPA 1963). Since Tokumitsu discloses compounds which contain the same structural elements as those claimed, they would be capable of performing the intended use, as claimed.

Claims 1, 4 – 7 and 9 – 13 are rejected under 35 U.S.C. 102(b) as being anticipated by Ranney *et al.* (US 5,155,215).

Ranney discloses the entrapment of paramagnetic metal-chelate complexes in biodegradable, hydrophilic polymeric microcarriers and their use in MR imaging. The chelate is chemically conjugated to hydrophilic polymers, such as dextran (column 7, lines 22 – 36). The chelating agent may be DTPA, DOTA, EDTA, etc. and the polymer is preferably dextran (column 7, lines 50 – 65). The paramagnetic metal ion is preferably gadolinium, and may also be manganese (claim 9). The chelate-polymer image-enhancing agents may be coupled to proteins, hormones, antibodies, etc. for

specific localization. The image-enhancing agents may be in soluble *or* microsphere form (column 9, lines 41 – 42). The microspheres are from 0.1 – 0.5 μm in size (see Example 3). Albumin microspheres containing entrapped, noncovalently bound metal-ion chelate complexes (e.g. Gd:DTPA) are also disclosed (see Example 12). Gd:DTPA microspheres containing non-covalently bound Gd:DTPA with strong ion pairing between DTPA and diethylaminoethylamine (DEAE) substituted dextan are also taught (see Example 13). With respect to the limitation in claim 1, wherein the particles are "administered as MR-Imaging Probes, administered in form of particulate which is internalized by cells where they are degraded enzymatically or by effectors in the environment surrounding them, giving rise to water soluble MR-Imaging Probes," it is noted that the instant claims are product claims and the recitation of method steps such as administering, etc. are not given patentable weight in product claims. The intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. See *In re Casey*, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 136 USPQ 458, 459 (CCPA 1963). Since Ranney discloses compounds which contain the same structural elements as those claimed, they would be capable of performing the intended use, as claimed.

Claims 1 – 3 and 6 are rejected under 35 U.S.C. 102(b) as being anticipated by Kabalka *et al.* (*Magnetic Res. In Medicine*, 1988, 8, p. 89 – 95).

Kabalka discloses gadolinium-labled liposomes as paramagnetic contrast agents. An amphipathic derivative of the chelating ligand diethylenetriaminepentaacetic acid is prepared, i.e. DTPA-SE, by conjugation of stearyl alcohol to DTPA via an ester bond (see Figure 1, page 90). Liposomes were formed mixing Gd-DTPA-SE, egg phosphatidylcholine, and cholesterol, and were then dried, vacuum desiccated, and resuspended in phosphate-buffered saline. The suspensions were sonicated to produce the desired small unilamellar vesicles with an average diameter of 0.05 μm (page 91). With respect to the limitation in claim 1, wherein the particles are "administered as MR-Imaging Probes, administered in form of particulate which is internalized by cells where they are degraded enzymatically or by effectors in the environment surrounding them, giving rise to water soluble MR-Imaging Probes," it is noted that the instant claims are product claims and the recitation of method steps such as administering, etc. are not given patentable weight in product claims. The intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. See *In re Casey*, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 136 USPQ 458, 459 (CCPA 1963). Since Kabalka discloses compounds which contain the same structural elements as those claimed, they would be capable of performing the intended use, as claimed.

Conclusion

No claims are allowed at this time.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Leah Schlientz whose telephone number is 571-272-9928. The examiner can normally be reached on Monday - Friday 8 AM - 5 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Hartley can be reached on 571-272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

LHS

MICHAEL G. HARTLEY
SUPERVISORY PATENT EXAMINER